PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
James R. Larkins et al.

Serial No.: 09/606,808

Filed: June 28, 2000

For: TRANSFORMABLE INBRED CORN LINE LIZL5 AND METHODS FOR USE THEREOF

Group Art Unit: 1638

Examiner: Mehta, A.

Atty. Dkt. No.: DEKA:264/REH

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April 7, 2003
Date

Robert E. Hanson

BRIEF ON APPEAL

TABLE OF CONTENTS

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BOX AF
Commissioner of Patents
Washington, D.C. 20231

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief. The fee for filing this Appeal Brief is attached hereto. This Brief is filed pursuant to the Notice of Appeal mailed January 31, 2003. The date for filing the instant Brief is April 7, 2003, based on the receipt of the Notice of Appeal by the Patent and Trademark Office on February 7, 2003. No fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/DEKA:264. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

There are no related interferences or appeals.

III. STATUS OF THE CLAIMS

Claims 1-39 were filed with the original application. Claims 1, 4, 7, 8, 10, 13, 18, 19 and 29 were amended in the Response to Office Action mailed in the case on January 2, 2002. Claims 9, 12, 19, 23 and 24 were amended in the Response to the Second Office Action mailed in the case on September 20, 2002 and the amendments subsequently entered. No claims have been canceled. Claims 1-39 were pending at the time of the final Office Action. Claims 1-21 and 29-36 were allowed in the final Office Action and claims 22-28 and 37-39 were rejected. A copy of appealed claims 22-28 and 37-39 is attached hereto as Appendix 1 and a copy of the pending claims is attached as Appendix 2.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the final Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated LIZL5 and seeds or populations of seed thereof. Specification at page 5, lines 8-22. The invention also relates to single locus converted plants of LIZL5. Specification at page 6, lines 8-21. The invention further relates to methods for breeding LIZL5 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 6 to page 8, line 2. The invention still further relates to

methods of transforming corn plant LIZL5 and the plants made thereby. Specification at page 9, lines 3-17.

VI. ISSUE ON APPEAL

Are claims 22-28 and 37-39 properly rejected under 35 U.S.C. §112, first paragraph, as not being supported by an adequate written description in the specification?

VII. GROUPING OF THE CLAIMS

Claims 22-24 are directed to hybrid seeds produced with corn plant LIZL5 as one parent or plants grown therefrom; whereas claims 25-28 are directed to corn plant LIZL5 comprising a single locus conversion and claims 37-39 are each independent and directed to different plants or seeds produced by transforming corn plant LIZL5. Claims 22-24 therefore stand or fall together, but stand or fall separately from the other appealed claims, which are directed to different classes of subject matter and present different issues under 35 U.S.C. §112, first paragraph. Claims 25-28 stand or fall together, but separately from the remaining appealed claims for the same reasons. Each of claims 37-39 stand or fall separately as being independent and directed to different plants or seeds produced by transforming corn plant LIZL5 and, therefore, presenting different issues under 35 U.S.C. §112, first paragraph.

VIII. SUMMARY OF THE ARGUMENT

Appellants have fully described the claimed subject matter. Each of the claimed hybrid plants and seeds having inbred corn plant LIZL5 as one parent have as half of their genome the same genetic contribution from LIZL5, given that corn plant LIZL5 is inbred. These plants therefore share this structural characteristic. The shared structural characteristic is fully

described in the specification by way of the detailed descriptions in the specification and the biological deposit of seed of LIZL5. Single locus conversions of LIZL5 and LIZL5 transformed with a transgene are also fully described in the specification by way of the description of LIZL5 and added traits.

IX. ARGUMENT

The Examiner has finally rejected claims 22-28 and 37-39 under 35 U.S.C. §112, first paragraph, as allegedly directed to subject matter which was not supported by a written description in the specification. In particular, the final Action alleges that the specification does not demonstrate possession of hybrid corn seed or plants prepared by crossing the inbred corn plant LIZL5 with a second corn plant or single locus conversions of corn plant LIZL5.

1. Appellants have fully described hybrid plants having LIZL5 as one parent

Rejected claims 22-24 are directed to hybrid plants and seeds produced with corn plant LIZL5 as one parent. Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history given at pages 24-25 of the specification, corn plant LIZL5 is an inbred corn plant. All of the claimed hybrid plants having LIZL5 as a parent will therefore contain a copy of the same genome as corn plant LIZL5. That is, because LIZL5 is an inbred corn plant, all hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant LIZL5. This entire genetic contribution of corn plant LIZL5 is described in the specification by way of the deposit of seed of corn plant LIZL5 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural

characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of the members of the claimed genus of hybrids having LIZL5 as one parent share the identical structural feature of having the genetic complement of LIZL5. One of skill in the art could thus readily identify the members of the genus. The written description requirement has therefore been fully complied with.

The Action attempts to downplay the significance of the genetic marker data by stating that some loci may be shared by other plants, that primer sequences are not described or that certain isozyme markers are not informative. However, no effort has been made to show that any substantial number of marker loci actually *are* shared by other plants. No basis has been provided to conclude that the claimed hybrid plants are not distinct and clearly identifiable by the genetic marker profile that has been set forth. Regarding the availability of genetic markers, the service that was used to detect SSR markers is commercially available to the public and SSR and any of the other genetic marker systems that are well known to those of skill in the art may be used, as is set forth on page 56 of the specification. Further, this is irrelevant given the written

description provided by the deposit of seed of LIZL5. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

Still further description of claimed hybrid plants is provided in the specification by way of a detailed description of hybrid 7026255, which was produced with LIZL5 as one inbred parent. Table 4 of the specification gives the performance characteristics for 7026255 and provides comparisons against other hybrid varieties. In Table 5, the morphological traits of 7026255 are given. Similarly, the SSR marker profile and isozyme marker profiles for hybrid 7026255 are given in Tables 8 and 9, respectively. This information, combined with the descriptions of the genetic and morphological characteristics of LIZL5 in the specification, as well as the fact that any hybrid derived from LIZL5 will contain half of its genes from LIZL5, is more than adequate to provide a description of hybrid plants and seeds derived from corn plant LIZL5 in compliance with the written description requirement.

2. The specification fully describes single locus conversion and transgenes

The final Office Action maintained the rejection of claims to single locus conversions of corn plant LIZL5, generally ignoring the substantial information put forth demonstrating written description of the claimed subject matter. In this regard, it is first noted that such a "single locus converted (conversion) plant" is defined at page 21, lines 6-11 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". Appellants have more than adequately described such a plant that comprises essentially

all of the desired morphological and physiological characteristics of corn plant LIZL5 by way of the description and deposit of LIZL5. To hold otherwise would be to limit Appellants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)) .

Appellants further note that substantial description is provided in the specification of transgenes and single locus conversions of LIZL5. For example, pages 29-32 describe numerous transgenic or conventional single locus traits for creation of single locus converted plants, including those conferring male sterility, waxy starch, herbicide resistance, resistance for bacterial, fungal, or viral disease, insect resistance, male fertility, enhanced nutritional quality, industrial usage, yield stability, and yield enhancement. Many of these traits are also described in PCT Application WO 95/06128, the disclosure of which is incorporated by reference in the current specification. The specification also provides examples of genes conferring male sterility, including those disclosed in U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, the disclosures of which were also incorporated by reference in the current application. Examples of male-sterility genes and corresponding restorers are also given by way of U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, each of the disclosures of which were incorporated by reference in the current application. Methods for selection of dominant single locus traits are also described at page 30, for example, such as a herbicide resistance trait.

Further described at page 30 of the specification are transgenic single locus conversions, including those created by electroporation (U.S. Patent No. 5,384,253), electrotransformation (U.S. Patent No. 5,371,003), microprojectile bombardment (U.S. Patent No. 5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765).

The use of a single locus trait conferring resistance to the herbicide glyphosate is described at page 31, including a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060), as well as a mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103). Methods for the use of these single locus conversions are also described at page 31. Further described, at page 32, are numerous transgenes for preparation of single locus conversions, including a selectable marker gene encoding phosphinothricin acetyl transferase (PPT) (*e.g.*, a bar gene), a gene encoding an endotoxin from *Bacillus thuringiensis* (Bt), and the waxy characteristic, each of which are well known to those of skill in the art. Still further, the specification describes, at pages 32-33, the origin and breeding history of an exemplary single locus converted plant, including all steps necessary for the preparation of the single locus converted plant.

The detailed description of these traits and of corn plant LIZL5 is more than adequate to provide a written description of the claimed subject matter. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, LIZL5. While Appellants

have not described every possible transgene or single locus conversion that could be introduced into corn plant LIZL5, this is not required under the written description requirement. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Well more than an adequate number of examples have been provided. These and many other such examples are well known to those of skill in the art. As such, Appellants have fully complied with the written description and removal of the rejection under 35 U.S.C. §112, first paragraph, is thus respectfully requested.

IX. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,

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APPENDIX 1: PENDING CLAIMS

1. Inbred corn seed of the corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

2. The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.

3. The inbred corn seed of claim 1, further defined as essentially free from hybrid seed.

4. An inbred corn plant produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

5. Pollen of the plant of claim 4.

6. An ovule of the plant of claim 4.

7. An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

8. A corn plant capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

9. The corn plant of claim 8, further comprising a cytoplasmic or nuclear gene conferring male sterility.

10. A tissue culture of regenerable cells of inbred corn plant LIZL5, wherein the tissue regenerates plants capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

11. The tissue culture of claim 10, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

12. The tissue culture of claim 11, wherein the regenerable cells are in the form of protoplasts or callus.

13. A corn plant regenerated from the tissue culture of claim 10, wherein said corn plant is capable of expressing all of the physiological and morphological characteristics of the inbred corn plant designated LIZL5, a sample of the seed of said inbred corn plant designated LIZL5 having been deposited under ATCC Accession No. PTA-2192.

14. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

15. A corn seed comprising the inbred corn plant cell of claim 14.

16. A tissue culture comprising the inbred corn plant cell of claim 14.

17. The inbred corn plant of claim 8, comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

18. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein said first or second corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192, wherein seed is allowed to form.

19. The process of claim 18, further defined as a process of producing hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein said first inbred corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

20. The process of claim 19, wherein crossing comprises the steps of:

(a) planting in pollinating proximity seeds of said first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) emasculating the male flowers of said first or second inbred corn plant to produce an emasculated corn plant;

(d) allowing cross-pollination to occur between said first and second inbred corn plants; and

(e) harvesting seeds produced on said emasculated corn plant.

21. The process of claim 20, further comprising growing said harvested seed to produce a hybrid corn plant.

22. Hybrid corn seed produced by the process of claim 20.

23. A corn plant produced by the process of claim 21.

24. The corn plant of claim 23, wherein the plant is a first generation (F_1) hybrid corn plant.

25. The corn plant of claim 4, further comprising a single locus conversion.

26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.

27. The corn plant of claim 25, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

28. The corn plant of claim 25, wherein the locus confers a trait selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal, nematode or viral disease, yield enhancement, waxy starch, improved nutritional quality, enhanced yield stability, male sterility and restoration of male fertility.

29. A method of preparing a transgenic maize cell comprising:

a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;

b) contacting said cells with a pre-selected DNA; and

c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

30. The method of claim 29, further comprising the step of:

d) regenerating a fertile transgenic plant from said transgenic cell.

31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

32. The method of claim 31, wherein said contacting comprises use of microprojectile bombardment.

33. The method of claim 31, wherein said contacting comprises use of PEG mediated transformation of protoplasts.

34. The method of claim 31, wherein said contacting comprises use of electroporation.

35. The method of claim 31, wherein said contacting comprises use of silicon carbide fiber mediated transformation.

36. The method of claim 31, wherein said contacting comprises use of *Agrobacterium*-mediated transformation.

37. A fertile transgenic maize plant preparable by the process of claim 30.

38. A seed of the fertile transgenic maize plant of claim 37, wherein said seed comprises said pre-selected DNA.

39. A plant grown from the seed of claim 38, said plant comprising said pre-selected DNA.

APPENDIX 2: APPEALED CLAIMS

22. Hybrid corn seed produced by the process of claim 20.

23. A corn plant produced by the process of claim 21.

24. The corn plant of claim 23, wherein the plant is a first generation (F_1) hybrid corn plant.

25. The corn plant of claim 4, further comprising a single locus conversion.

26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.

27. The corn plant of claim 25, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

28. The corn plant of claim 25, wherein the locus confers a trait selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal, nematode or viral disease, yield enhancement, waxy starch, improved nutritional quality, enhanced yield stability, male sterility and restoration of male fertility.

37. A fertile transgenic maize plant preparable by the process of claim 30.

38. A seed of the fertile transgenic maize plant of claim 37, wherein said seed comprises said pre-selected DNA.

39. A plant grown from the seed of claim 38, said plant comprising said pre-selected DNA.